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Uptake, feasibility, cost and cost effectiveness of universal screening for gestational diabetes mellitus in primary care

Submission date
31/08/2012

Recruitment status
No longer recruiting

Registration date
27/09/2012

Overall study status
Completed

Last Edited
27/11/2015

Condition category
Pregnancy and Childbirth

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Gestational diabetes mellitus (GDM) is a type of diabetes that affects women during pregnancy. It is common and is associated with serious complications for the mother and baby. While the need for GDM screening is broadly accepted, there is a debate as to what form this should take, with some advocating universal screening of all pregnant women and others selective screening of high-risk subgroups only. The aim of this study is to find out whether screening all pregnant women for GDM in primary care is clinically effective and cost effective.

Who can participate?
Pregnant women visiting the maternity clinic at Galway University Hospitals (GUH) at 18-20 weeks gestation.

What does the study involve?
Participants are randomly allocated to either primary care or secondary care screening for GDM. All women are invited for an oral glucose tolerance test (a test for GDM) at 24-28 weeks gestation.
In the primary care screening group, women are tested in their local GP clinic. In the secondary care screening group, women are tested in the maternity unit at GUH. All women with GDM are offered consultations with a dietician and a diabetes nurse specialist and are instructed to self-monitor their blood sugar levels over the remainder of their pregnancy. Women who do not respond to lifestyle changes after two weeks are prescribed insulin for the remainder of their pregnancy. Data is collected to examine how well screening works in primary care compared to screening in secondary care.

What are the possible benefits and risks of participating?
Not provided at time of registration.

When is the study starting and how long is it expected to run for?
October 2012 to September 2014.

Who is funding the study?
This study is funded by the Health Research Board (HRB), an Irish government agency.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NA

Study information

Scientific Title
Uptake, feasibility, cost and cost effectiveness of universal screening for gestational diabetes mellitus in primary care

Study objectives
The aim of the study is to evaluate the clinical and cost effectiveness of universal screening for gestational diabetes mellitus in primary care.

Null hypothesis:
There is no difference between universal screening for gestational diabetes mellitus in primary care and secondary care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Research Ethics Committee, Galway University Hospital, 03/08/2012, ref: C.A. 753

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Gestational diabetes mellitus

Interventions
The target population for the study includes all women, ordinarily resident in the Galway University Hospitals (GUH) catchment area, who present with pregnancy . Following recruitment, eligible women will be randomized to either the primary care or secondary care screening groups. All women who consent to participate in the study, regardless of their randomized screening group, will be invited for a 2-hour 75g oral glucose tolerance test (OGTT) at between 24-28 weeks gestation. The process of care for each group will differ only in terms of the setting where testing is provided:

Primary Care Screening Group: All women randomized to this group will be tested in their local GP clinic. Following randomization, a study researcher will notify each woman that her screening will be conducted at the GP clinic. In addition, a letter, Study Information Sheet, and a GDM Screening Test Pack will be sent to the woman's GP. The GP will be asked to contact the woman to attend the clinic for the purposes of conducting an OGTT at between 24-28 weeks gestation. The GP will be asked to perform the OGTT using the materials provided and, as per usual care, to send the test sample to the laboratory at GUH for analysis.

Secondary Care Screening Group: All women randomized to this group will be tested in the maternity unit at GUH. Following randomization, a study researcher will notify each woman that their screening will be conducted at the hospital. A study researcher will send the name of the woman to the maternity clinic with the instruction to contact the woman to attend the clinic for the purposes of conducting an OGTT at between 24-28 weeks gestation. As per usual care, the test samples will be sent to the laboratory at GUH for analysis.

Laboratory Analysis, Diagnosis and Patient Notification
All test samples will be analyzed at the laboratory at GUH. Each ATLANTIC DIP study test sample will have a study-specific label to enable identification. The Roche Modular Analytics <P> Chemistry Systems will be employed to measure plasma glucose. The hexokinase method is used and is based on the work of Schmidt, Peterson and Young, is a recognized reference method.

GDM will be defined according to the new International Association of Diabetes and Pregnancy Study Groups (IADPSG) criteria (IADPSG, 2010). We will apply the cut-off values for a diagnosis of GDM of: fasting, 1 hour or 2 hour glucoses ≥5.1mmol/l (92mg/dl), 10mmol/l (180mg/dl) or 8.5 mmol/l (153mg/dl) respectively.

Primary Care Screening Group: As per usual care, the laboratory will send the test results directly to the GP clinic and the GP will inform the woman of her result. For positive test results, the GP will be directed to contact the maternity clinic at GUH to make an appointment to initiate an appropriate GDM treatment regimen. The maternity clinic will be requested to make an

appointment at the GDM clinic for those women diagnosed with GDM and to inform them of same.

Secondary Care Screening Group: As per usual care, the laboratory will send the test results directly to the maternity clinic that in turn will inform the woman of her result. The maternity clinic will be requested to make an appointment at the GDM clinic for those women diagnosed with GDM and to inform them of same. For positive test results, the woman will be contacted to attend the maternity unit to initiate an appropriate GDM treatment regimen.

Post Screening: Diagnosis, GDM Treatment, Antenatal Care, Delivery, and Neonatal Care
All women with positive results will be contacted by the maternity clinic to attend the hospital for GDM treatment. This will involve lifestyle intervention, blood glucose self-monitoring and, if required, insulin. In terms of lifestyle intervention, all women with GDM will be offered consultations with a dietician and/or a diabetes nurse specialist. In terms of self-monitoring, all women will be instructed to self-monitor over the remainder of their pregnancy. Women who do not respond to lifestyle intervention after two weeks will be prescribed insulin for the remainder of their pregnancy. Antenatal care for women with GDM will be provided by specialists in diabetes and obstetrics in secondary care and by GPs in primary care. All deliveries will take place at the maternity unit at GUH where the process of care may consist of normal vaginal delivery, assisted vaginal delivery (including forceps and/or ventose), elective caesarean section, and/or emergency caesarean section delivery. Where necessary, an infant of a woman with GDM may be admitted to the neonatal intensive care unit at GUH.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Uptake of screening offer

Key secondary outcome(s))
1. GDM prevalence
2. Timing of screening
3. Access to antenatal diabetes care for women with GDM
4. Pregnancy Outcomes for women with GDM:
4.1. Maternal Outcomes: mode of delivery [vaginal delivery (normal or assisted), caesarean section (emergency or elective)), hypertensive, disorders of pregnancy (gestational hypertension and pre-eclampsia), polyhydramnios, and ante and postpartum haemorrhage.
4.2. Neonatal Outcomes: live birth rate, congenital malformation rate; premature delivery (defined as delivery before 37 weeks gestation); birthweight; macrosomia (defined as birthweight >4 kg); large for gestational age; small for gestational age; admission to neonatal intensive care unit; duration of stay in neonatal intensive care unit; Apgar score at 5 min; shoulder dystocia; neonatal hypoglycaemia; neonatal jaundice; and neonatal respiratory distress
5. Economic Outcomes:
5.1. Costs of Care
5.2. Quality Adjusted Life Years (QALYs)
5.3. Incremental Cost per QALY gained

Completion date

30/09/2014

Eligibility

Key inclusion criteria
Women who present with pregnancy at the maternity clinic at Galway University Hospitals (GUH)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Pregnant women with pre-diagnosed diabetes or pre-diagnosed gestational diabetes mellitus

Date of first enrolment
01/10/2012

Date of final enrolment
30/09/2014

Locations

Countries of recruitment
Ireland

Study participating centre
National University of Ireland
Galway
Ireland
Eire

Sponsor information

Organisation
Health Research Board (Ireland)

ROR

https://ror.org/003hb2249

Funder(s)

Funder type
Government

Funder Name
Health Research Board (Ireland)

Alternative Name(s)
HRB

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Ireland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2015		Yes	No
Protocol article	protocol	17/01/2014		Yes	No